

2019

Impact assessment of new US Food and Drug Administration regulations on antibiotic use: A post-enactment survey of swine practitioners

Christopher J. Rademacher
Iowa State University, cjrsvm@iastate.edu

Christopher C. Pudenz
Iowa State University, ccpudenz@iastate.edu

Lee L. Schulz
Iowa State University, lschulz@iastate.edu

Follow this and additional works at: https://lib.dr.iastate.edu/econ_las_pubs



Part of the [Agricultural and Resource Economics Commons](#), [Design of Experiments and Sample Surveys Commons](#), [Large or Food Animal and Equine Medicine Commons](#), and the [Veterinary Preventive Medicine, Epidemiology, and Public Health Commons](#)

The complete bibliographic information for this item can be found at https://lib.dr.iastate.edu/econ_las_pubs/698. For information on how to cite this item, please visit <http://lib.dr.iastate.edu/howtocite.html>.

This Article is brought to you for free and open access by the Economics at Iowa State University Digital Repository. It has been accepted for inclusion in Economics Publications by an authorized administrator of Iowa State University Digital Repository. For more information, please contact digirep@iastate.edu.

Impact assessment of new US Food and Drug Administration regulations on antibiotic use: A post-enactment survey of swine practitioners

Abstract

Following a 2016 pre-enactment survey, 42 swine veterinary practitioners were surveyed in 2017 to assess post-enactment impacts of the revised Veterinary Feed Directive (VFD). The survey evaluated veterinarian-client-patient relationships, client recruitment, VFD fees and creation, record keeping, education and training, business costs, and changes in antibiotic usage and on-farm management.

Keywords

swine, veterinary feed directive, economics, antibiotics

Disciplines

Agricultural and Resource Economics | Design of Experiments and Sample Surveys | Large or Food Animal and Equine Medicine | Veterinary Preventive Medicine, Epidemiology, and Public Health

Comments

This article is published as Rademacher CJ, Pudenz CC, Schulz LL. Impact assessment of new US Food and Drug Administration regulations on antibiotic use: A post-enactment survey of swine practitioners. *J Swine Health Prod.* 2019;27(4):210–220. Posted with permission.

Impact assessment of new US Food and Drug Administration regulations on antibiotic use: A post-enactment survey of swine practitioners

Christopher J. Rademacher, DVM; Christopher C. Pudenz, BA; Lee L. Schulz, PhD

Summary

Following a 2016 pre-enactment survey, 42 swine veterinary practitioners were surveyed in 2017 to assess post-enactment impacts of the revised Veterinary Feed Directive (VFD). The survey evaluated veterinarian-client-patient relationships, client recruitment, VFD fees and creation, record keeping, education and training, business costs, and changes in antibiotic usage and on-farm management.

Keywords: swine, veterinary feed directive, economics, antibiotics

Received: August 16, 2018

Accepted: February 6, 2019

Resumen - Evaluación del impacto de las nuevas regulaciones de la Administración de Alimentos y Medicamentos de los Estados Unidos sobre el uso de antibióticos: Una encuesta post-promulgación a los veterinarios especialistas en cerdos

Después de una encuesta previa a la promulgación en 2016, en 2017 se encuestó a 42 veterinarios especialistas en cerdos para evaluar los impactos post-promulgación de la Directiva Veterinaria de los Alimentos revisada (VFD). La encuesta evaluó las relaciones veterinario-cliente-paciente, el reclutamiento de clientes, las tarifas y la creación de la VFD, el registro de datos, la educación y la capacitación, los costos comerciales y los cambios en el uso de antibióticos y en el manejo en la granja.

Résumé – Évaluation de l'impact des nouvelles réglementations du US Food and Drug Administration sur l'utilisation des antibiotiques: Un sondage post-promulgation des praticiens porcins

À la suite du sondage pré-promulgation réalisé en 2016, 42 vétérinaires praticiens porcins ont été sondés de nouveau en 2017 pour évaluer les impacts post-promulgation des directives vétérinaires sur les aliments (Veterinary Feed Directive, VFD). Le sondage a évalué les relations vétérinaire-client-patient, le recrutement de clients, la création et les frais de VFD, la tenue de dossier, l'éducation et la formation, les coûts d'affaire, et les changements dans l'utilisation d'antibiotiques et la gestion à la ferme.

On April 13, 2012, the US Food and Drug Administration (FDA) issued Guidance for Industry (GFI) 209 “to inform the public of FDA’s current thinking on the use of medically important antimicrobial drugs in animal agriculture.”^{1,2} On December 12, 2013, FDA issued GFI 213 to provide “information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA’s Guidance for Industry (GFI) #209” and to “set timelines for stakeholders wishing to comply voluntarily with this guidance.”^{3,4} On June 3, 2015, FDA issued the revised Veterinary Feed Directive (VFD) which “established requirements relating to

the distribution and use of VFD drugs and animal feeds containing such drugs,”⁵ and became effective on October 1, 2015. Full implementation of FDA’s GFIs and VFD final rule was set for December 2016 with enforcement commencing on January 1, 2017.

The GFIs and VFD final rule direct the use of medically important antibiotics (defined as antibiotics that are important for therapeutic use in human medicine) in livestock for therapeutic purposes only. Therapeutic purposes are defined as either treatment, control, or prevention of disease.² These policies are focused on use of medically important antibiotics given in mass medication

formats, either through the feed or the water. Use of medically important antibiotics in feed requires a VFD order from the veterinarian to the producer and feed manufacturer. Medically important antibiotics used in water requires a veterinary prescription. Another aim of these policies was to require that if producers wanted to use medically important antibiotics, they could only do so under the guidance of a veterinarian with a valid veterinarian-client-patient relationship (VCPR). This endows the veterinarian with the responsibility for making medical decisions for the farm, with the producer bearing responsibility in following the medical directions of the veterinarian. Another aim of these policies was to eliminate the use of medically important antibiotics for growth promotion use. Collectively, these new regulations have changed the ways that antibiotics are used in livestock production.

From a 2016 survey of practicing swine veterinarians on VFD preparation, Schulz and Rademacher⁶ reported that extensive preparation and education was being done by veterinarians and their producers to help ensure a smooth transition to the new antibiotic-use guidelines. The results also

CJR: Department of Veterinary Diagnostic and Production Animal Medicine, Iowa State University, Ames, Iowa.

CCP, LLS: Department of Economics, Iowa State University, Ames, Iowa.

Corresponding author: Dr Christopher J. Rademacher, Department of Veterinary Diagnostic and Production Animal Medicine, 2215 Lloyd Veterinary Medicine Center, Iowa State University, Ames, IA, 50011; Tel: 515-294-8792; Fax: 515-294-3838; Email: cjrdvm@iastate.edu.

This article is available online at <http://www.aasv.org/shap.html>.

Rademacher CJ, Pudenz CC, Schulz LL. Impact assessment of new US Food and Drug Administration regulations on antibiotic use: A post-enactment survey of swine practitioners. *J Swine Health Prod.* 2019;27(4):210–220.

suggested that there were varying views on the definition of a VCPR, plans for meeting the additional record keeping requirement and delivery of VFDs, fees associated with providing VFDs, costs to swine veterinary business operations, and reduction in the use of antibiotics in feed as a result of the VFD. A follow-up survey was conducted in 2017 to assess post-enactment impacts of the revised VFD.

Materials and methods

The survey protocol was approved by the Iowa State University Institutional Review Board (IRB ID 16-489) prior to distribution of the survey. Data collection procedures for this study were similar to those used for the 2016 survey as described by Schulz and Rademacher.⁶ Questions from the 2016 survey were revised to reflect post-January 1, 2017 status of the new antibiotic-use guidelines. In addition, new questions were added to the survey to elicit information on the fee structure for writing VFDs and prescriptions, the level of production (ie, group or lot, site, flow, or system), and average number of pigs for which a VFD was written. The data for this study are from a convenience sample of practicing swine veterinarians. Swine veterinary practitioners attending the 2017 Iowa State University (ISU) James D. McKean Swine Disease Conference held in Ames, Iowa, on November 2-3, 2017 were surveyed. The conference attracts veterinarians, students, academic faculty and staff, and allied industry personnel. Of the 305 conference attendees, 125 practicing swine veterinarians were identified at conference check-in and given a paper survey.

To increase survey response and expand distribution, input was sought from ISU faculty and staff who were familiar with swine production systems and swine-focused veterinary clinics to identify additional practicing swine veterinarians to be surveyed. A convenience sample of 35 practicing swine veterinarians from the upper Midwest region of the United States who did not attend the conference were surveyed electronically using Qualtrics (Qualtrics, Provo, Utah). The Qualtrics survey questionnaire sent to practicing swine veterinarians was identical to the one distributed at the conference. A customized email invitation for the Qualtrics survey was sent on November 16, 2017 with reminders sent to non-respondents on 2 occasions 1 week apart. The Qualtrics survey was closed on December 18, 2017.

Data retrieved from returned surveys were compiled and summarized using descriptive statistics.

After several introductory questions gathering practitioner demographic (ie, location, experience) and clientele base (ie, independent, contractor, or contract grower; phase of production; annual pig sales) information, the practitioners surveyed were asked a series of questions about how the VFD requirements impacted their business operations as well as swine production in general. Specifically, questions targeted veterinarian-client-patient relationships, client recruitment, VFD fees and creation, record keeping, education and training, business costs, and changes in antibiotic usage and on-farm management.

Results

Response rate and respondent profile

The response rate for the survey distributed at the ISU James D. McKean Swine Disease Conference was 23.2%, 29 of 125 practitioners who received a paper survey returned a completed survey. Thirteen of 35 practitioners who received a Qualtrics survey returned a completed survey, a 37.1% response rate. Therefore, there were 42 practicing swine veterinarians in the final sample. However, a few participants only partially completed the survey. The number of respondents for each question of interest are presented in Tables 1 through 12.

Comprehensive questions about veterinarian demographic details (eg, private vs corporate practice or employed by an integrator) were not included in the survey and, therefore, it cannot be confirmed if the study sample is representative of the entire practicing swine veterinarian population. Respondents' primary geographic location were in states with the largest number of swine operations and inventories: 24 veterinarians practiced in Iowa and 9 in Minnesota. Other states represented include Illinois (3 respondents), Indiana (2 respondents), Kansas (1 respondent), Missouri (1 respondent), and Nebraska (1 respondent). According to the 2012 US Census of Agriculture, these states represent 30% of US swine operations and 67% of the US pig inventory.⁷

The average number of hogs marketed annually by the responding veterinarians' clientele were 0 (1.5% of clients), 1 to 4999 (13.1%

of clients), 5000 to 19,999 (23.0% of clients), 20,000 to 49,999 (23.2% of clients), and 50,000 or more (39.2% of clients). For the 7 states represented, 74% of all operations have annual sales of 1 to 4999 hogs, while 26% of operations have annual sales of 5000 or more hogs according to the 2012 US Census of Agriculture.⁷ Thus, the clients served by the veterinarians within our sample had larger operations than the census averages.

The largest percentage of swine clients served by veterinarians had farrow-to-finish production (39.2%), followed by wean-to-finish (21.3%), breeding-farrowing (18.8%), finishing (12.2%), nursery (5.6%), gilt developer unit (2.7%), boar stud (0.2%), and other (0.1%). The largest segment of swine clients were independent producers (64.5%), followed by contractors or integrators (21.7%) and contract growers (13.8%).

These general demographic characteristics of the survey participants suggests a reasonable degree of representation of clients served by veterinarians was achieved despite use of convenience recruitment techniques. However, due to not asking certain questions in the survey and the small sample size, we were not able to make comparisons across several factors that characterize the entire population of swine veterinary practitioners. Therefore, the study results may not be generalizable to all practicing swine veterinarians and may not represent the entire US swine industry. Nonetheless, this work reports one of the first attempts to track progress toward adjusting to the new antibiotic-use guidelines.

Veterinarian-client-patient relationship

All respondents were aware of their respective state's VCPR definition. Twenty-one of the 41 responding veterinarians (51.2%) believed that only 1 visit per year was needed to maintain a VCPR, whereas 11 veterinarians (26.8%) thought 2 visits and 7 veterinarians (17.1%) thought 4 visits were needed to maintain a VCPR (Table 1). Two veterinarians replied that they did not know how many visits were required to have a VCPR. One common concern often voiced from practicing veterinarians was an obligation to make site visits solely for the purpose of writing VFDs. More than half of 41 survey respondents (24 veterinarians; 58.5%) felt as though they were conducting more site

visits per operation with the new VFD regulations. Veterinarians were asked how many sites within an operation they felt were necessary to visit to fulfill the VCPR requirements. The majority of respondents (26 of 41; 63.4%) felt it necessary to visit all sites, while 14 respondents (34.1%) felt that they had to visit more than 1 site, but not all sites. Only 1 veterinarian replied

that visiting 1 site was sufficient to satisfy the VCPR requirement. These results differ somewhat from the 2016 survey responses where a larger proportion of veterinarians (56.0%) envisioned visiting 2 or more sites, but not all sites, compared to the proportion (40.0%) that anticipated visiting all sites.

Client recruitment

Regarding client recruitment, 17 veterinarians (41.5%) reported being approached by new clients for the purpose of writing VFDs (Table 2). Fourteen veterinarians (34.1%) accepted new clients that approached them specifically to provide VFDs, but only 6 of them (14.6%) admitted to actively recruiting new clients to meet minimum requirements

Table 1: Survey questions regarding the veterinarian-client-patient relationship*

	No. reporting	% reporting
How many visits in a year do you think is required for a swine producer and veterinarian to have a VCPR? (n = 41)		
1 visit	21	51.2
2 visits	11	26.8
3 visits	0	0.0
4 visits	7	17.1
5 visits	0	0.0
6 or more visits	0	0.0
I don't know	2	4.9
Have you made more visits per operation to write VFDs? (n = 41)		
Yes	24	58.5
No	17	41.5
In order to fulfill the VCPR requirement for a producer how many sites do you visit? (n = 41)		
1 site	1	2.44
2 or more sites (but not all sites)	14	34.15
All Sites	26	63.41

* A convenience sample of practicing swine veterinarians attending the 2017 ISU James D. McKean Swine Disease Conference or who practice in the upper Midwest region of the United States were surveyed regarding their opinions of the impact of the new antibiotic-use guidelines on pork production and the practice of swine veterinary medicine during the first year of enforcement. Forty-two completed or partially completed surveys were returned.

VCPR = veterinarian-client-patient relationship; VFD = Veterinary Feed Directive; ISU = Iowa State University.

Table 2: Survey questions regarding client recruitment*

	No. reporting	% reporting
Have you been approached by new potential clients due to the VFD? (n = 41)		
Yes	17	41.5
No	24	58.5
Have you accepted new clients that approached you specifically to provide VFDs? (n = 41)		
Yes	14	34.1
No	27	65.9
Have you recruited new clients specifically to meet minimum requirements to provide VFDs? (n = 41)		
Yes	6	14.6
No	35	85.4

* Study details are described in Table 1.
VFD = Veterinary Feed Directive.

to provide VFDs. These results would only apply to veterinarians working for veterinary clinics. Prior to the new regulations, there were anecdotal reports of some producers who would purchase their medically important antibiotics over-the-counter from local feed suppliers rather than routinely use veterinarians. Once VFDs or prescriptions were required for antibiotic administration of a medically important antibiotic to a population of pigs, it is reasonable to hypothesize that the client pool for veterinarians increased.

VFD fees

The mean fee per VFD written for existing clients was \$23.75 and for new clients was \$24.19 (Table 3). Only 36 and 31 veterinarians, respectively, responded to this question which is most likely due to some respondents being employed by production companies and therefore do not charge for VFDs they write. Based on client operation size, a median difference of approximately \$2.50 to \$5.00 per VFD was found for operations who marketed between 1 and 49,999 pigs. Similarly, a median difference of \$2.50 to \$7.50 per prescription was observed across

client operation sizes (Table 3). In general, it appears that veterinarians charged clients with larger operations more for VFDs and prescriptions. Thirty-five of the 40 responding veterinarians (87.5%) that are charging for a VFD include this expense as a separate line item in their invoice. When compared to veterinarians who also write prescriptions, only 21 of the 37 responding veterinarians (56.8%) include prescriptions as a separate line item, rather than writing prescriptions as part of a consultation or service fee.

Table 3: Survey responses regarding VFD and prescription fees for new and existing clients*†

	Type of client	No. reporting	Cost, mean (SD), \$	Cost, median, \$
1 to 4999 marketings/year				
VFD	New	0	NR	NR
	Existing	1	20.00 (NA)	20.00
Prescription	New	0	NR	NR
	Existing	1	20.00 (NA)	20.00
5000 to 19,999 marketings/year				
VFD	New	6	20.42 (4.01)	20.00
	Existing	8	22.19 (4.90)	22.50
Prescription	New	4	13.75 (4.79)	12.50
	Existing	4	16.25 (4.79)	17.50
20,000 to 49,999 marketings/year				
VFD	New	23	24.89 (6.05)	25.00
	Existing	24	23.65 (6.47)	25.00
Prescription	New	11	21.36 (7.45)	20.00
	Existing	10	20.50 (7.62)	20.00
≥ 50,000 marketings/year				
VFD	New	0	NR	NR
	Existing	1	35.00 (NA)	35.00
Prescription	New	0	NR	NR
	Existing	0	NR	NR
All respondents				
VFD	New	31‡	24.19 (5.82)	25.00
	Existing	36‡	23.75 (6.17)	25.00
Prescription	New	15	19.33 (7.53)	20.00
	Existing	15	19.33 (6.78)	20.00

* Study details are described in Table 1.

† The survey instrument collected swine-client marketings per year using categorical variables, ie, the percentage that would fall into each size category: 1 to 4999; 5000 to 19,999; 20,000 to 49,999; or 50,000 or more. For this analysis, the midpoint of each category (and end-point of the upper and lower bound category) was used to calculate the weighted average marketings per year.

‡ Two survey respondents did not report swine client marketings per year but did report VFD charges for new and existing clients; these responses are included in "all respondents."

VFD = Veterinary Feed Directive; NR = none reported; NA = not applicable.

VFD creation

Veterinary Feed Directives can be written for various levels of production. When the 42 respondents were asked for which level of production they most frequently wrote VFDs, 18 (42.9%) responded the pig flow level, while 12 (28.6%) responded the site level and 9 (21.4%) responded the group or lot level (Table 4). The mean number of pigs covered by a written VFD was 5916 pigs with a median of 2600 and a standard deviation of 9070 (Table 5). Over half of the respondents (22 of 39) wrote VFDs for 2400 to 9999 pigs, while 11 (28.2%) respondents wrote VFDs for fewer than 2400 animals and 6 respondents (15.4%) wrote VFDs for more than 9999 animals. To generate VFDs, veterinarians predominately used an electronic VFD service (34 of 41; 82.9%) but had also made their own VFDs (7 of 41;

17.1%) or used a VFD form from a drug sponsor (4 of 41; 9.8%) (Table 6). For drug prescriptions, most veterinarians responded that they used a form they had created (28 of 41; 68.3%), while others used an electronic prescription service (13 of 41; 31.7%) or a prescription form provided by a drug sponsor (4 of 41; 9.8%).

VFD record keeping

Veterinary Feed Directives must be retained for 2 years by the producer, feed distributor, and the veterinarian. Almost two-thirds of the 41 responding veterinarians (63.4%) had used a third-party service (eg, Global Vet-Link [GVL]) in order to meet this requirement, while 11 (26.8%) used existing staff (Table 7). Independent of how the VFD was generated, veterinarians reported to have delivered VFDs to producers via a third-party

electronic service (28 of 41; 68.3%), email (22 of 41; 53.7%), hard copies (18 of 41; 43.9%), fax (12 of 41; 29.3%), and method of producer (8 of 41; 19.5%) or feed supplier (6 of 41; 14.6%) preference.

Education and training

Since the implementation of the new guidelines, veterinarians and staff had attended meetings (including webinars) (34 of 41; 82.9%), read literature (32 of 41; 78.0%), and created information bulletins to distribute to staff (13 of 41; 31.7%) to learn about the VFD requirements (Table 8). To help educate their clients, veterinarians sponsored in-clinic meetings (including webinars) (16 of 40; 40.0%), met with clients in person (35 of 40; 87.5%), sent a notice of requirements in a regularly published newsletter (20 of 40; 50.0%), and created

Table 4: Survey responses regarding the level of production for which a VFD was most frequently written*

Marketings/year†	Level of production, No. (%)			
	Group or lot	Site	Flow	System
1 to 4,999	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)
5000 to 19,999	0 (0.0)	3 (37.5)	5 (62.5)	0 (0.0)
20,000 to 49,999	7 (26.9)	7 (26.9)	10 (38.5)	2 (7.7)
≥ 50,000	1 (20.0)	0 (0.0)	3 (60.0)	1 (20.0)
All respondents	9 (21.4)‡	12 (28.6)‡	18 (42.9)	3 (7.1)

* Study details are described in Table 1.

† The survey instrument collected swine-client marketings per year using categorical variables, ie, the percentage that would fall into each size category: 1 to 4999; 5000 to 19,999; 20,000 to 49,999; or 50,000 or more. For this analysis, the midpoint of each category (and endpoint of the upper and lower bound category) was used to calculate the weighted average marketings per year.

‡ Two survey respondents did not report swine client marketings per year but did report the level of production they most often write a VFD for; this response is included in "all respondents."

VFD = Veterinary Feed Directive.

Table 5: Survey responses regarding the number of pigs per VFD*

	No. reporting	Mean (SD)	Median
	39	5916 (9070)	2600
Average No. of pigs	No. reporting (%)		
< 1200	5 (12.8)		
1200 to 2399	6 (15.4)		
2400 to 4999	15 (38.5)		
5000 to 9999	7 (17.9)		
10,000 to 19,999	3 (7.7)		
≥ 20,000	3 (7.7)		

* Study details are described in Table 1.

VFD = Veterinary Feed Directive.

Table 6: Survey questions regarding types of VFD and prescription forms used*

	No. reporting	% reporting†
Have you used a pre-made VFD form or created your own? (n = 41)		
Used electronic VFD service (eg, GVL)	34	82.9
Used VFD form provided by a drug sponsor	4	9.8
Created VFD form for your clinic	7	17.1
Other	0	0.0
Have you used a pre-made prescription form or created your own? (n = 41)		
Used electronic prescription service (eg, GVL)	13	31.7
Used prescription form provided by a drug sponsor	4	9.8
Created prescription form for your clinic	28	68.3
Other	0	0.0

* Study details are described in Table 1.

† Percentages may reflect multiple answers from individual survey respondents.

VFD = Veterinary Feed Directive; GVL = Global VetLink.

Table 7: Survey questions regarding record keeping and VFD delivery to producers*

	No. reporting	% reporting†
FDA requires a record of every VFD be kept for a period of 2 years. What have you done to meet the additional record keeping requirement? (n = 41)		
No changes	4	9.8
Used existing staff	11	26.8
Hired new staff	1	2.4
Used a third-party service (eg, GVL)	26	63.4
Other	0	0.0
How do you provide VFDs to producers? (n = 41)		
Whatever the producer prefers	8	19.5
Whatever the feed supplier prefers	6	14.6
Third party electronic service (eg, GVL)	28	68.3
Fax	12	29.3
Email	22	53.7
Hard copies	18	43.9
Other	0	0.0

* Study details are described in Table 1.

† Percentages may reflect multiple answers from individual survey respondents.

VFD = Veterinary Feed Directive; FDA = Food and Drug Administration; GVL = Global VetLink.

an information bulletin (15 of 40; 37.5%). The frequency of updated training on VFD requirements varied, but the largest percentage of respondents believed updated training should occur annually for both staff (26 of 40; 65.0%) and clients (26 of 39; 66.7%).

Cost of VFD regulation implementation

When evaluating the business costs associated with VFD regulation implementation, there were more non-responders (n = 19) than for most of the other survey questions. This is most likely due to responding veterinarians either being employed by production companies or being young, associate veterinarians

who are not involved in the financial dealings of the clinic. Six survey respondents (14.6%) had 1 to 5 years of experience in swine veterinary practice and an additional 6 respondents (14.6%) had 6 to 10 years of experience.

Descriptive statistics and distribution of annual cost estimates regarding writing and delivery of VFDs, maintaining records for

Table 8: Survey questions regarding education and training on VFD requirements*

	No. reporting	% reporting†
Since January 1, 2017, what have you done to educate yourself and staff on VFD requirements? (n = 41)		
I (we) have not done any education in 2017	4	9.8
Attended meetings (including webinars) to learn more about the VFD	34	82.9
Read literature on the VFD	32	78.0
Created an information bulletin on the VFD to distribute to staff	13	31.7
Other	0	0.0
Since January 1, 2017, what have you done to educate your swine clients on VFD requirements? (n= 40)		
I (we) have not done any education in 2017	4	10.0
Sponsored in-clinic meetings (including webinars) to present information and discuss requirements	16	40.0
Met in-person with clients to discuss requirements	35	87.5
Sent a notice of requirements to clients in a regular newsletter	20	50.0
Created an information bulletin to distribute to clients	15	37.5
Other	0	0.0

* Study details are described in Table 1.

† Percentages may reflect multiple answers from individual survey respondent.
VFD = Veterinary Feed Directive.

VFDs, educating clients and others (eg, nutritionists and feed suppliers), training staff on VFD requirements, and other components are presented in Table 9. Writing and delivering VFDs was the largest annual cost across all respondents with a mean value of \$4051 and a median value of \$3000. The annual cost for maintaining VFD records was similar in expense with a mean value of \$3561 and a median value of \$1000. The lowest annual cost to business operations was training staff on VFD requirements (mean of \$787; median of \$500). Costs recorded in the “other” category by 2 respondents were listed as the cost of the GVL software and additional staff required to write and store the VFDs. Generally, the costs slightly increased as client operation size increased, most likely due to the increase in the number of VFDs that would be written annually.

Table 10 shows the perceived amount of burden the respondents felt that VFD requirement compliance has had on veterinarians, feed suppliers, producers, and consulting nutritionists. Overall, burden to comply with the VFD is considered moderate. The highest amount of burden is believed to be on feed suppliers followed closely by producers and veterinarians.

Impact of antibiotic-use regulations

The reality of FDA’s antibiotic-use guidelines is that producers and veterinarians have had more conversations about judicious antibiotic use of medically important antibiotics in feed or water. Overall, a perceived reduction in the amount of antibiotics used was reported, however, the magnitude of the reduction varied. The largest percentage of responding veterinarians (9 of 20; 22.5%) indicated a 21% to 30% perceived reduction in the use of antibiotics in feed by their clients as a result of the new antibiotic regulations (Table 11). Thirteen (32.5%) respondents perceived a 51% to 100% reduction of antibiotic use in feed among their clients. Swine veterinarians also reported a perceived increase in the amount of injectable (19 of 40 respondents; 47.5%) and water-soluble antibiotics used (30 of 41 respondents; 73.2%) since the VFD regulations were implemented.

Management changes due to regulations

One of the most important changes in the new regulations was the removal of medically important antibiotics for growth promotion. In response, it appears that most clients dealt with this change by eliminating all uses of antibiotics for growth promotion (58.8%), while another 17.0% of clients

reduced use of antibiotics for growth promotion (Table 12). About 24% of clients changed to the use of non-medically important antibiotics for growth promotion. These results were different than those reported in the 2016 survey where veterinarians were predominately recommending replacing the medically important antibiotics with non-medically important antibiotics for growth promotion (52.9%).⁶

Responding veterinarians (n = 37) reported that increased vaccinations (30; 81.1%) were the primary management change made due to the new antibiotic regulations. Increasing non-antibiotic feed additives (21; 56.8%), modifying biosecurity (18; 48.6%), and modifying nutrition (14; 37.8%) were other common responses. One of the concerns veterinarians had during the previous survey regarding the new regulations was having enough documentable evidence to justify their recommendations to use medically important antibiotics. Thirty-nine of the 41 responding veterinarians in the present survey (95.1%) felt they had collected the needed health diagnostic information to defend or justify their antibiotic-use recommendations.

Discussion

On January 1, 2017, GFIs 209 and 213 and the revised VFD took effect. With a 3-year

Table 9: Survey responses regarding per year costs to veterinary business operations*†

	No. reporting	Cost, mean (SD), \$	Cost, median, \$
5000 to 19,999 marketings/year			
Writing and delivering VFDs	5	2860 (2796)	2400
Maintaining records for VFDs	2	1000 (0)	1000
Educating clients and others on the VFD requirements	3	433 (493)	200
Training staff on VFD requirements	2	300 (283)	300
Per year for other	0	NR	NR
20,000 to 49,999 marketings/year			
Writing and delivering VFDs	12	4143 (3700)	2800
Maintaining records for VFDs	7	4659 (9133)	1000
Educating clients and others on the VFD requirements	7	822 (862)	300
Training staff on VFD requirements	9	895 (877)	500
Per year for other‡	1	3600 (NA)	3600
≥ 50,000 marketings/year			
Writing and delivering VFDs	3	5667 (3786)	4000
Maintaining records for VFDs	1	1000 (NA)	1000
Educating clients and others on the VFD requirements	2	3500 (3536)	3500
Training staff on VFD requirements	0	NR	NR
Per year for other	0	NR	NR
All respondents			
Writing and delivering VFDs	20	4051 (3446)	3000
Maintaining records for VFDs	10	3561 (7663)	1000
Educating clients and others on the VFD requirements	12	1171 (1673)	650
Training staff on VFD requirements	11	787 (826)	500
Per year for other‡	2§	11,800 (11,597)	11,800

* Study details are described in Table 1.

† The survey instrument collected swine-client marketings per year using categorical variables, ie, what percentage would fall into each size category: 1 to 4999; 5000 to 19,999; 20,000 to 49,999; or 50,000 or more. For this analysis, the midpoint of each category (and endpoint of the upper and lower bound category) was used to calculate the weighted average marketings per year. One respondent had swine clients with 1 to 4999 marketings per year but did not report costs to veterinary business operations.

‡ Costs listed in this category were GVL software cost and hired employee to spend ½ time writing VFDs.

§ One survey respondent did not report swine client marketings per year but did report per year other costs to veterinary business operations; this response is included in "all respondents."

VFD = Veterinary Feed Directive; NR = none reported; NA = not applicable; GVL = GlobalVetLink.

implementation timeline from the time the GFIs were published, these regulations had already begun to influence antibiotic-use practices. According to the FDA 2016 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, sales of medically important antibiotics decreased by 14%.⁸ Sales to US swine producers made up 37% of the medically important antibiotics that were sold

to livestock in 2016, so it is reasonable to assume that a portion of this overall decrease was in preparation for the new regulations to take effect. In 2016, there were many conversations among veterinarians and regulatory officials about how many visits to each site would fulfill the VCPR definition of timely visits. Some states have defined what constitutes timely, whereas others have not. Our survey results were varied with 51.2% of veterinarians thinking an annual visit would

suffice, but the rest of the respondents felt it would take 2 or 4 visits per year to be considered timely. Many swine owners today have pigs that are raised on many different sites. Most of the veterinarians surveyed felt that they needed to visit all sites to have a valid VCPR, but there was a significant number of veterinarians that felt they needed to visit more than one site, but not all sites, within the operation to be in compliance.

Table 10: Survey responses regarding the perceived burden to comply with VFD requirements*

Population	Perceived burden, No. reporting (%)			
	No burden	Little burden	Moderate burden	Very burdensome
Veterinarians	0 (0.0)	14 (34.1)	24 (58.5)	3 (7.3)
Feed suppliers	0 (0.0)	6 (14.6)	24 (58.5)	11 (26.8)
Producers	2 (4.9)	16 (39.0)	21 (51.2)	2 (4.9)
Consulting nutritionists	5 (12.8)	20 (51.3)	14 (35.9)	0 (0.0)

* Study details are described in Table 1.
VFD = Veterinary Feed Directive

Table 11: Survey questions on perceived reduction in antibiotic usage due to new regulations*

	No. reporting (%)
What percentage have your swine producers reduced the use of antibiotics in feed as a result of the VFD? (n = 40)	
0%	0 (0.0)
1% to 10%	4 (10.0)
11% to 20%	7 (17.5)
21% to 30%	9 (22.5)
31% to 40%	1 (2.5)
41% to 50%	6 (15.0)
51% to 60%	1 (2.5)
61% to 70%	4 (10.0)
71% to 80%	4 (10.0)
81% to 90%	0 (0.0)
91% to 100%	4 (10.0)

In your opinion, how has the VFD changed the use of antimicrobials in water and injectable in US swine production?

Water (n = 41)	
Increased	30 (73.2)
Decreased	2 (4.9)
Not changed	8 (19.5)
I do not know	1 (2.4)
Injectable (n = 40)	
Increased	19 (47.5)
Decreased	1 (2.5)
Not changed	18 (45.0)
I do not know	2 (5.0)

* Study details are described in Table 1.
VFD = Veterinary Feed Directive.

For those veterinarians who charge for writing VFDs, the mean fee for both new and existing clients was approximately \$24 per VFD (median fee of \$25), in contrast to an anticipated fee of \$27 to \$30 per VFD based on the 2016 survey.⁶ The standard deviation was also cut in half compared to the 2016 survey, indicating that charges for VFDs are much more consistent across the industry. Prescription prices were less than the price of VFDs (median value of \$20). While most of the VFDs are listed as a separate line item on a veterinary invoice, it is more common for prescriptions to be included as part of a consultation fee.

There is a fair amount of variation regarding what level of production a VFD is written for. Flow (generally defined as pigs that originated from the same breeding herd but raised in several different locations after weaning) was the most common production level, but there were many veterinarians who wrote VFDs specifically for the site and some even down to the individual lot level. Most veterinarians surveyed used an electronic service to both issue and store written VFDs. However, many veterinarians surveyed still used computer-generated forms rather than utilizing an electronic prescription service.

These survey results provide evidence that the new regulations have resulted in a perceived decreased usage of antibiotics in feed. The most common response was a 21% to 30% perceived decrease in antibiotic usage, but nearly a third of respondents believe that the reduction is anywhere from 50% to 100%. One of the biggest changes in antibiotic usage was their overall removal for growth promotion. In the 2016 survey, the majority of respondents predicted that their clients would shift from medically important to non-medically important antibiotics for growth promotion as there are several products now

available and new products being evaluated. It appears though, that most of their clients eliminated either all or part of their antibiotics used for growth promotion, thus most likely contributing to the overall decrease in antibiotic usage.

Due to this survey using a convenience sample, there are some limitations to this data. There is certainly potential for biases based on the sampling technique and the geographic region from which the sample was derived. The readers should take this into consideration and not extrapolate the results of this survey to the entire US swine industry. The low response rate also necessitates caution when interpreting results. It is unknown whether collecting survey responses by type of veterinary practice, eg, private vs corporate practice or employed by a large integrator, would have affected the results. However, the swine veterinary practice demographics collected did demonstrate variability and responses were from US states with the highest concentration of swine production. Informed by these results, future surveys should employ a randomized questionnaire distribution method and include questions to provide a more complete picture of how the antibiotic-use guidelines continue to impact pork production and the practice of swine veterinary medicine in the United States.

Implications

- Improved veterinarian oversight of antibiotics used in US swine production was a key response from survey participants.
- Survey respondents reported the occurrence of more discussions between swine veterinarians and producers about the use of antibiotics and antibiotic alternatives.
- Survey respondents perceived a reduction of antibiotic use in feed as a result of the VFD regulations.

Acknowledgments

Conflict of interest

None reported.

Disclaimer

Scientific manuscripts published in the *Journal of Swine Health and Production* are peer reviewed. However, information on medications, feed, and management techniques may be specific to the research or commercial situation presented in the manuscript. It is the responsibility of the reader to use information responsibly and in accordance with the rules and regulations governing research or the practice of veterinary medicine in their country or region.

References

- *1. Guidance for Industry on the judicious use of medically important antimicrobial drugs in food-producing animals; Availability. *Fed Regist.* 2012;77(72):22328-22329.
- *2. US Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine. Guidance for Industry #209, The judicious use of medically important antimicrobial drugs in food producing animals. April 13, 2012. <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>. Accessed June 6, 2017.
- *3. Guidance for Industry on new animal drugs and new animal drug combination products administered in or on medicated feed or drinking water of food-producing animals: Recommendations for drug sponsors for voluntarily aligning product use conditions with Guidance for Industry #209; Availability. *Fed Regist.* 2013;78(239):75570-75571.
- *4. US Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine. Guidance for Industry #213, New animal drugs and new animal drug combination products administered in or on medicated feed or drinking water of food-producing animals: Recommendations for drug sponsors for voluntarily aligning product use conditions with GFI #209. December 2013. <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM279624.pdf>. Accessed June 6, 2017.
- *5. Veterinary Feed Directive; Final Rule. *Fed Regist.* 2015;80(106):31708-31735. To be codified at 28 CFR §514 and §558.

Table 12: Survey questions regarding management changes made to address antibiotic regulations and growth promotion use*

	No. reporting	Mean (SD), %	Median, %
Percentage of swine clients who:			
Eliminated all uses of antibiotics for growth promotion	38	58.8 (42.3)	66.9
Reduced use of antibiotics for growth promotion	38	17.0 (29.2)	0.0
Moved to non-medically important growth promotants	38	24.2 (33.4)	7.5
Other	38	0.0 (0.0)	0.0
	No. reporting	% reporting†	
Changes producers have made (n = 37)			
Modified biosecurity	18	48.6	
Increased vaccinations	30	81.1	
Increased non-antibiotic feed additives	21	56.8	
Modified nutrition	14	37.8	
Modified housing	6	16.2	
Modified animal purchase strategies	5	13.5	
Modified population density	3	8.1	
Other	0	0.0	

* Study details are described in Table 1.

† Percentages may reflect multiple answers from individual survey respondents.

6. Schulz LL, Rademacher CJ. Food and Drug Administration Guidance 209 and 213 and Veterinary Feed Directive regulations regarding antibiotic use in livestock: A survey of preparation and anticipated impacts in the swine industry. *J Swine Health Prod.* 2017;25(5):247-255.

*7. US Department of Agriculture, National Agricultural Statistics Service. 2012 census of agriculture, United States summary and state data. http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf. Published May 2014. Accessed June 6, 2017.

*8. US Food and Drug Administration. 2016 summary report on antimicrobials sold or distributed for use in food-producing animals. <https://www.fda.gov/downloads/forindustry/userfees/animal-druguserfeeactadufa/ucm555085.pdf>. Published December 2017. Accessed July 9, 2018.

* Non-refereed references.



CONVERSION TABLES

Weights and measures conversions

Common (US)	Metric	To convert	Multiply by
1 oz	28.35 g	oz to g	28.4
1 lb (16 oz)	453.59 g	lb to kg	0.45
2.2 lb	1 kg	kg to lb	2.2
1 in	2.54 cm	in to cm	2.54
0.39 in	1 cm	cm to in	0.39
1 ft (12 in)	0.31 m	ft to m	0.3
3.28 ft	1 m	m to ft	3.28
1 mi	1.6 km	mi to km	1.6
0.62 mi	1 km	km to mi	0.62
1 in ²	6.45 cm ²	in ² to cm ²	6.45
0.16 in ²	1 cm ²	cm ² to in ²	0.16
1 ft ²	0.09 m ²	ft ² to m ²	0.09
10.76 ft ²	1 m ²	m ² to ft ²	10.8
1 ft ³	0.03 m ³	ft ³ to m ³	0.03
35.3 ft ³	1 m ³	m ³ to ft ³	35
1 gal (128 fl oz)	3.8 L	gal to L	3.8
0.264 gal	1 L	L to gal	0.26
1 qt (32 fl oz)	946.36 mL	qt to L	0.95
33.815 fl oz	1 L	L to qt	1.1

Temperature equivalents (approx)

°F	°C
32	0
50	10
60	15.5
61	16
65	18.3
70	21.1
75	23.8
80	26.6
82	28
85	29.4
90	32.2
102	38.8
103	39.4
104	40.0
105	40.5
106	41.1
212	100

$$^{\circ}\text{F} = (^{\circ}\text{C} \times 9/5) + 32$$

$$^{\circ}\text{C} = (^{\circ}\text{F} - 32) \times 5/9$$

Conversion chart, kg to lb (approx)

Pig size	Lb	Kg
Birth	3.3-4.4	1.5-2.0
Weaning	7.7	3.5
	11	5
	22	10
Nursery	33	15
	44	20
	55	25
	66	30
Grower	99	45
	110	50
	132	60
Finisher	198	90
	220	100
	231	105
	242	110
	253	115
Sow	300	135
	661	300
Boar	794	360
	800	363

1 tonne = 1000 kg

1 ppm = 0.0001% = 1 mg/kg = 1 g/tonne

1 ppm = 1 mg/L